



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94945d

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

WARNING LETTER

August 19, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stephen Cheng, President
Window Rock Enterprises, Inc.
601 Valencia Ave., Suite 150
Brea, CA 92823

W/L 44-04

Dear Mr. Cheng:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your firm, Window Rock Enterprises, Inc., located at 601 Valencia Avenue, Suite 150, Brea, CA 92823, on April 5th and April 7th, 2004. During this inspection, you provided our investigator with the following promotional materials for your product CortiSlim, which are shipped to customers with the product:

- CortiSlim Brochure
- CortiSlim Information Sheet (includes supplement facts, ingredients, and directions for use)
- Cortisol Stress Test
- CortiSlim Instant Savings and Money Back Guarantee Certificate
- CortiSlim Quick Start Guide

Our investigator also collected information, including copies of scientific research and studies, you provided to substantiate the claims made for your product CortiSlim. In addition, after our inspection of your firm, we reviewed labeling for CortiSlim on your website at <http://www.cortislim.com>.

VIOLATIONS

A review of your labeling for CortiSlim, including the promotional materials listed above, indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321 *et seq.*). Specifically, we have determined that your CortiSlim product is misbranded under sections 403(r)(6)(B) and 403(a)(1) of the Act (21 U.S.C. §§ 343(r)(6)(B); 343(a)(1)) because the product's labeling includes unsubstantiated claims. Under the Act, as amended by the

Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with claims to affect the structure or function of the body (structure/function claims), if certain requirements are met (21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(g)). The manufacturer of a dietary supplement containing a “structure/function” claim in the product’s labeling must have substantiation that the claim is truthful and not misleading (*see* 21 U.S.C. § 343(r)(6)(B)). You can find the Act and FDA regulations on the Internet through links on FDA's web page: www.fda.gov.

Examples of some of the structure/function claims made in the labeling for your CortiSlim product include:

- CortiSlim Product Label: “Eliminate Cravings,” “Controls Appetite”
- CortiSlim Brochure: “Ease ‘stress eating,’” “Suppresses appetite,” “Burn calories more efficiently and naturally through thermogenesis,” “Controls cortisol levels within a healthy range,” “control appetite,” “reduce cravings”
- CortiSlim Quick Start Guide: “curb appetite and cravings,” “weight loss solution”
- CortiSlim Instant Savings and Money Back Guarantee Certificate: “lose weight,” “reduce cravings for carbohydrates and sweets,” “take the edge off your appetite,” “enhance metabolism through thermogenesis”
- Cortisol Stress Test: “cravings for sweets and carbohydrates will diminish”
- Website:
 - Under “The SENSE Program,” Exercise topic section: “appetite control”
 - Under the “Ingredients” section: “controls cortisol levels within healthy range and help[s] you lose weight,” “control appetite,” “helps to reduce cravings”
 - Under the “FAQ (frequently asked questions)” section: “reduce cravings,” “Appetite and craving control,” “weight loss,” “control appetite”
 - Under the “User Guide” section: “curb appetite and cravings”

We have reviewed these claims, along with the substantiation package you provided, and concluded that they are not supported by reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of section 403(a)(1) and 403(r)(6)(B) of the Act. It is a violation of section 301(a) of the Act (21 U.S.C. § 331(a)) to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded.

This letter is not intended to provide an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm comply with applicable United States laws, including the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by FDA without further notice. The Act provides for seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

You must notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised labeling for

CortiSlim should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

ADDITIONAL COMMENTS

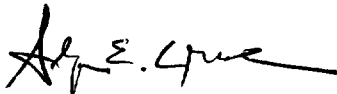
During the April 2004 inspection, you provided our investigator with information to substantiate the following claims for CortiSlim:

- “supports healthy cortisol levels”
- “supports weight maintenance efforts”

Although these claims do not appear to be used in your current labeling for CortiSlim, we have reviewed them because they were referred to in your substantiation package. Based on the information provided in your substantiation package, we conclude that these claims are not supported by reliable scientific evidence. Unless you have additional information that would adequately substantiate these claims, any present or future use of such claims in the CortiSlim labeling would misbrand your product under sections 403(r)(6)(B) and 403(a)(1) of the Act.

Your written reply should be addressed to Compliance Officer John Stamp at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alonza E. Cruse', with a stylized flourish at the end.

Alonza E. Cruse
District Director